

## REMARKS

This preliminary amendment is submitted to correct formatting errors in the international application as-filed and to conform both the specification and claims to United States practice. Original claims 1-33, which included multiple dependent claims, have been canceled, and new claims 34-60 have been added. Pursuant to 37 C.F.R. § 1.125 and MPEP 608.01(q), both a clean copy of a substitute specification (Appendix A) and a marked-up copy of the substitute specification showing all changes to the prior version of record (Appendix B) are submitted herewith. Applicants respectfully submit that no new matter has been added to the substitute specification or new claims 34-60. It is respectfully requested that the above amendments be entered and made of record in the file of the present application.

No additional fees are believed due with this submission. However, should any additional fees be required, please charge such fees to Jones Day deposit account No. 50-3013.

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**Appendix B**  
**Marked-Up Copy of Substitute Specification (attached)**

**Amendment**

## INTRAMEDULLARY NAIL

### FIELD OF THE INVENTION

[0001] This invention concerns an intramedullary nail [in accordance with the pre-characterising portion of Claim 1.]and, more particularly, an intramedullary nail having a plurality of transverse holes extending through a distal end of the nail.

### BACKGROUND OF THE INVENTION

[0002] Such a nail is [know]known from [the]German patent publication DE-C-3 244 243 to ENDER, which discloses a rigid intramedullary nail having two through holes at the distal end of the nail and whose direction is not parallel and not orthogonal and which is further defined in the specification to be at an acute angle, e.g., of 10° or 60°.

[0003] A further nail is known from [U.S. 5,041,115]United States Patent No. 5,041,115 to FRIGG [ET AL. ]et al., which discloses an intramedullary nail having three through holes at the distal end of the nail which are disposed at 90° to each other.

[0004] A disadvantage of the known nails is the fact that the distal holes are unnecessarily far from the distal nail tip which produces a nail-weakening effect, and prevents engagement in very short [far]distal fragments.

[0005] A further disadvantage of the known nails having parallel holes spaced closely to one another (i.e., known [nails]nail hole spacings equal to [3,5]3.5(d)) is the fact that holes in the bone surface are too close to one another.

[0006] Still a further disadvantage is that widely spaced parallel or orthogonal holes offer the surgeon limited options in the choice of the position of the screws, such as might be necessary to avoid neurovascular structures.

[0007] A further disadvantage of these known nails is the fact that there is an unnecessary loose fit to the hole in the nail by the screws which traverse the nail. This allows a toggling of the traversing screw in the hole, in turn allowing an increased torsional twisting and other motion at the fracture site.

[0008] The invention as claimed aims at solving the above described problems/disadvantages and also [in order]aims to facilitate secure attachment in short fragments at the [far]distal end of the intramedullary nail.

### SUMMARY OF THE INVENTION

[0009] The present invention provides an intramedullary nail [as defined in Claim 1.]comprising a nail body having a longitudinal axis, a proximal end configured and

dimensioned for coupling to an insertion device, and a distal end having a tip configured and dimensioned for insertion into the intramedullary canal of a long bone. At least three transverse holes extend through the distal end of the nail body, with each transverse hole defining a hole axis, and all three transverse holes grouped at the distal end within a distance  $x$  measured from the tip of the nail body to the axis of the transverse hole furthest from the tip. A projection of the three hole axes of the at least three transverse holes in a plane orthogonal to the longitudinal axis is such that at least two of the projected hole axes are at an angle  $\alpha$  with respect to one another, where  $0 < \alpha < 90^\circ$ , and where the distance  $x \leq 25d$ , where  $d$  is either the diameter of the largest of the at least three transverse holes or  $d$  is the mean diameter of the at least three holes.

[0010] Surprisingly, mechanical and clinical studies undertaken by the inventor, have revealed that of two different intramedullary nails having the same number of traversing holes clustered near the distal tip of the nail, the one with holes clustering closed to the tip of the nail is less likely to face failure through a screw hole than the intramedullary nail with greater hole spacing. Furthermore unused holes between the nail tip and  $x$ -position do not weaken the nail more than does the  $x$ -position hole. This is true for the same diameter.

[0011] The  $x$ -position hole is the hole in the far half of the intramedullary nail which is farthest from the tip of the nail.

[0012] The multiple hole/close spacing intramedullary nail according to the invention can be used for all known applications, i.e., proximal fracture, extreme distal fracture, ankle fusion and correction of deformity and therefore replaces all known nails with one single type, making storage much simpler and less costly. It maximizes the number of screws which can be placed near the tip of the nail, increasing the surface contact area between the hardware and the bone.

[0013] The invention offers the following advantages:

[0014] 1) it prevents adjacent screws from having their bone cortex holes too close to one another[.]; — thereby reducing crack propagation between these bone cortex holes[.];

[0015] 2) it gives the surgeon different anatomical position options for placement of screws to provide more secure bony fixation or to allow avoidance or neurovascular structures[.]; and

[0016] 3) it controls angular motion of the fragment which respect to the intramedullary nail by way of a greater possible number of screws, screws in multiple directions, and closer fit of the screws in the holes.

[0017] In a preferred embodiment of the intramedullary nail, the distance  $x$  measured from the tip of the nail to the axis of the hole most distant from the tip is equal or smaller than  $25d$ , preferably equal or smaller than  $7d$ ,  $d$  being the diameter of the holes.

[0018] In a preferred embodiment of the invention the projected hole axes of at least two of said through holes are at an angle  $\alpha$  of approx.  $30^\circ$ ,  $36^\circ$ ,  $45^\circ$  or  $60^\circ$  or multiples thereof.

[0019] Preferably a number of  $n > 4$  holes are grouped in the far end of the nail within a distance  $x$  which is smaller than  $2(n)(d)$ ,  $d$  being the diameter of the holes. More preferably the value for  $x$  is smaller than  $[1,5]1.5(n)(d)$ .

[0020] In a preferred embodiment the value of  $n$  for the number of holes is 5 or 6.

[0021] At least two through holes may be located in such a way that the geometric hollow cylinders, as defined by these holes, intersect with one another, preferably with intersecting axes of these cylinders. The two intersecting through holes may be located at the same distance  $d$  from said tip of the nail and preferably are spaced  $88^\circ - 92^\circ$  apart. In the above specified formulae for the distance  $x$  the two holes which intersect, only one should be included in the number  $n$  of holes.

[0022] In order to facilitate a more secure fixation with the interlocking screw having an outer thread at least one of the through holes may be provided with a matching internal thread. This facilitates more secure fixation with the interlocking screw having a matching outer thread.

[0023] Furthermore a portion of one or more screw holes may be substantially conical in geometry.

[0024] The intramedullary nail has preferably a solid cross-section, but may have alternatively a tubular cross-section.

[0025] Preferably all holes are located in planes orthogonal to the longitudinal axis of the nail.

[0026] The distance ( $a$ ) between the tip of the nail and that through hole which nearest to the tip (7) may be ( $a$ )  $\leq 5d$ , and preferably ( $a$ )  $\leq [1,5]1.5d$ , whereby  $d$  is the diameter of the through hole.

[0027] In a preferred embodiment a plurality of  $n$  through holes are provided in the nail whose centres are located at a distance  $x$  from said tip which is comprised in the range of

$$[1,05]1.05(n)(d) \leq x \leq [3,00]3.00(n)(d)$$

[0028] In a further preferred embodiment a plurality of  $n$  through holes are provided in the nail whose centres are located at a distance  $x$  from the tip which is smaller than  $4d + (n-1)([2,2]2.2d)$ .

[0029] Preferably the distance " $b$ " between the axes of two adjacent through holes is  $b \leq [1,5]1.5d$ .

[0030] The intramedullary nail according to the invention may comprise an interlocking screw which has a diameter equal or larger than  $[0,9]0.9$  times the hole diameter into which it is inserted; preferably the diameter is equal or larger than  $[0,94,]0.94$ , most preferably  $[0,96]0.96$  times the hole diameter into which it is inserted.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0031] In the drawings:

[0032] Fig. 1 is a side view of the intramedullary nail according to the invention;

[0033] Fig. 2 is an enlarged detailed view of the far end of intramedullary nail of Fig. 1;

[0034] Fig. 3 is an enlarged detailed view of the far end of intramedullary nail showing the core where holes intersect;

[0035] Fig. 4 is the same view of Fig. 3 rotated by  $90^\circ$ ;

[0036] Fig. 5 is section along the line V-V of Fig. 3; and

[0037] Fig. 6 is a representation of a plane orthogonal to the longitudinal axis of the nail with projections of the [axis]axes of the through holes showing the various angles at which the through holes traverse the nail.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0038] Figure 1 shows an intramedullary nail with a solid cross-section having a longitudinal axis 5. The longitudinal axis 5 may be curved along a portion of the nail if the nail itself is curved in that portion. The intramedullary nail further comprises a near end 1 with means 8 consisting of an internally threaded bore for coupling to an insertion device and a far end 2 with a tip 7 for insertion into the intramedullary canal of a long bone. The far end 2 is provided with four traversing through holes 3 with axes 6, all of said through holes 3 being grouped in said far end 2 within a distance  $x$  measured from said tip 7 to the axis 6 of the most distant hole 3 (as indicated by the arrow in Fig. 1).

[0039] The projection of the hole axis 6 of said through holes 3 in a plane orthogonal to said longitudinal axis 5 (or if the hole axis 6 - as shown in the figures - is lying already in an orthogonal plane, the hole axis itself) is such that at least two of said (projected) hole axes 6 are

at an angle  $\alpha$  greater than zero and less than  $90^\circ$  with respect to each other. In Fig. 2 the angle  $\alpha$  is approximately  $60^\circ$ .

[0040] In the nail according to Figs. 1 and [2]2, a number  $n$  of four holes 3 is grouped in said far end 2 within a distance  $x$  which is smaller than the product of  $2(n)(d)$ ,  $d$  being the diameter of said holes 3.

[0041] In Figs. 3 to 5 an embodiment is shown in which two of said through holes 3 are located in such a way that the geometric hollow cylinders, as defined by said holes 3, intersect with one another. In particular the two intersecting through holes 3 have intersecting axes 6 and are located at the same distance " $a$ " from the tip 7. The two holes 3 are located in an orthogonal plane to said longitudinal axis 5 and are spaced at an angle  $\alpha$   $90^\circ$  apart.

[0042] Fig. 6 shows a representation of a plane orthogonal to the longitudinal axis 5 of the nail 1 with projections of the axis 6 of the through holes 3 showing the various angles  $\alpha_1$ ,  $\alpha_2$ , and  $\alpha_3$  in orthogonal projection at which the through holes 3 traverse the nail 1. The angles  $\alpha_1$ ,  $\alpha_2$ , and  $\alpha_3$  may be in the range of  $30^\circ$  to  $60^\circ$  according to the anatomy requirements.

[0043] While the present invention has been described with reference to the preferred embodiments, those skilled in the art will recognize that numerous variations and modifications may be made without departing from the scope of the present invention. Accordingly, it should be clearly understood that the embodiments of the invention described above are not intended as limitations on the scope of the invention, which is defined only by the following claims.